

Appl. No. 10/627,198
Amendment dated July 21, 2005
Reply to Office action of January 21, 2005

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-38 (Cancelled)

Claim 39 (new) A granule formulation comprising 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof and a freely or very water-soluble binder, wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns and wherein the granules have a moisture level in the range of 1.5% to 15%.

Claim 40 (new) A formulation according to claim 39 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo[b,f][1,4]thiazepine is in the form of a fumarate salt.

Claim 41 (new) A formulation according to claim 39 wherein the freely or very water-soluble binder comprises maltodextrin, mannitol, xylitol, pre-gelatinised starch, sucrose or poly[1-(2-oxo-1-pyrrolidinyl)ethylene].

Claim 42 (new) A formulation according to claim 40 wherein the freely or very water-soluble binder comprises maltodextrin, mannitol, xylitol, pre-gelatinised starch, sucrose or poly[1-(2-oxo-1-pyrrolidinyl)ethylene].

Claim 43 (new) A formulation according to claim 41 wherein the binder is maltodextrin.

Claim 44 (new) A formulation according to claim 42 wherein the binder is maltodextrin.

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Claim 45 (new) A formulation according to claim 39 which further comprises a sweetener.

Claim 46 (new) A formulation according to claim 40 which further comprises a sweetener.

Claim 47 (new) A formulation according to claim 41 which further comprises a sweetener.

Claim 48 (new) A formulation according to claim 42 which further comprises a sweetener.

Claim 49 (new) A formulation according to claim 43 which further comprises a sweetener.

Claim 50 (new) A formulation according to claim 44 which further comprises a sweetener.

Claim 51 (new) A formulation according to claim 39 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 52 (new) A formulation according to claim 40 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 53 (new) A formulation according to claim 41 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 54 (new) A formulation according to claim 42 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 55 (new) A formulation according to claim 43 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 56 (new) A formulation according to claim 44 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 57 (new) A formulation according to claim 45 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

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Claim 58 (new) A formulation according to claim 46 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 59 (new) A formulation according to claim 47 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 60 (new) A formulation according to claim 48 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 61 (new) A formulation according to claim 49 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 62 (new) A formulation according to claim 50 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 63 (new) A granule formulation consisting of 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzol[b,f][1,4]thiazepine or a pharmaceutically acceptable salt thereof, a freely or very water-soluble binder, and a sweetener wherein the granules have a bulk density range of 0.15 g/cc to 0.60 g/cc and a tap density range of 0.20 g/cc to 0.70 g/cc and 80% of the granules are in the size range of 75 to 850 microns and wherein the granules have a moisture level in the range of 1.5% to 15%.

Claim 64 (new) A formulation according to claim 63 wherein 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzol[b,f][1,4]thiazepine is in the form of a fumarate salt.

Claim 65 (new) A formulation according to claim 63 wherein the freely or very water-soluble binder comprises maltodextrin, mannitol, xylitol, pre-gelatinised starch, sucrose or poly[1-(2-oxo-1-pyrrolidinyl)ethylene].

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Claim 66 (new) A formulation according to claim 64 wherein the freely or very water-soluble binder comprises maltodextrin, mannitol, xylitol, pre-gelatinised starch, sucrose or poly[1-(2-oxo-1-pyrrolidinyl)ethylene].

Claim 67 (new) A formulation according to claim 65 wherein the binder is maltodextrin.

Claim 68 (new) A formulation according to claim 66 wherein the binder is maltodextrin.

Claim 69 (new) A formulation according to claim 64 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 70 (new) A formulation according to claim 65 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 71 (new) A formulation according to claim 66 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 72 (new) A formulation according to claim 67 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 73 (new) A formulation according to claim 68 wherein the bulk density range is 0.26 g/cc to 0.400 g/cc and the tap density range is 0.342 g/cc to 0.500 g/cc.

Claim 74 (new) A formulation according to claim 39 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 75 (new) A formulation according to claim 40 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 76 (new) A formulation according to claim 41 wherein the granules have a moisture level in the range of 4% and 8%.

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Claim 77 (new) A formulation according to claim 42 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 78 (new) A formulation according to claim 43 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 79 (new) A formulation according to claim 44 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 80 (new) A formulation according to claim 45 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 81 (new) A formulation according to claim 46 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 82 (new) A formulation according to claim 47 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 83 (new) A formulation according to claim 48 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 84 (new) A formulation according to claim 49 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 85 (new) A formulation according to claim 50 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 86 (new) A formulation according to claim 51 wherein the granules have a moisture level in the range of 4% and 8%.

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Claim 87 (new) A formulation according to claim 52 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 88 (new) A formulation according to claim 53 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 89 (new) A formulation according to claim 54 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 90 (new) A formulation according to claim 55 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 91 (new) A formulation according to claim 56 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 92 (new) A formulation according to claim 57 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 93 (new) A formulation according to claim 58 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 94 (new) A formulation according to claim 59 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 95 (new) A formulation according to claim 60 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 96 (new) A formulation according to claim 61 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 97 (new) A formulation according to claim 62 wherein the granules have a moisture level in the range of 4% and 8%.

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Claim 98 (new) A formulation according to claim 63 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 99 (new) A formulation according to claim 64 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 100 (new) A formulation according to claim 65 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 101 (new) A formulation according to claim 66 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 102 (new) A formulation according to claim 67 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 103 (new) A formulation according to claim 68 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 104 (new) A formulation according to claim 69 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 105 (new) A formulation according to claim 70 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 106 (new) A formulation according to claim 71 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 107 (new) A formulation according to claim 72 wherein the granules have a moisture level in the range of 4% and 8%.

Claim 108 (new) A formulation according to claim 73 wherein the granules have a moisture level in the range of 4% and 8%.

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Claim 109 (new) A formulation according to claim 39 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 110 (new) A formulation according to claim 40 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 111 (new) A formulation according to claim 41 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 112 (new) A formulation according to claim 42 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 113 (new) A formulation according to claim 43 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 114 (new) A formulation according to claim 44 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 115 (new) A formulation according to claim 45 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 116 (new) A formulation according to claim 46 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 117 (new) A formulation according to claim 47 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 118 (new) A formulation according to claim 48 wherein the granules have a moisture level in the range of 3% and 10%.

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Claim 119 (new) A formulation according to claim 49 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 120 (new) A formulation according to claim 50 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 121 (new) A formulation according to claim 51 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 122 (new) A formulation according to claim 52 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 123 (new) A formulation according to claim 53 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 124 (new) A formulation according to claim 54 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 125 (new) A formulation according to claim 55 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 126 (new) A formulation according to claim 56 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 127 (new) A formulation according to claim 57 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 128 (new) A formulation according to claim 58 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 129 (new) A formulation according to claim 59 wherein the granules have a moisture level in the range of 3% and 10%.

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Claim 130 (new) A formulation according to claim 60 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 131 (new) A formulation according to claim 61 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 132 (new) A formulation according to claim 62 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 133 (new) A formulation according to claim 63 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 134 (new) A formulation according to claim 64 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 135 (new) A formulation according to claim 65 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 136 (new) A formulation according to claim 66 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 137 (new) A formulation according to claim 67 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 138 (new) A formulation according to claim 68 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 139 (new) A formulation according to claim 69 wherein the granules have a moisture level in the range of 3% and 10%.

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Claim 140 (new) A formulation according to claim 70 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 141 (new) A formulation according to claim 71 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 142 (new) A formulation according to claim 72 wherein the granules have a moisture level in the range of 3% and 10%.

Claim 143 (new) A formulation according to claim 73 wherein the granules have a moisture level in the range of 3% and 10%.